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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/830,189 | 04/21/2004 | Brian S. Kelleher | 028US2 | 7725 |

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| EXAMINER | |
|---|---|
| SZMAL, BRIAN SCOTT | |
| **ART UNIT** | **PAPER NUMBER** |
| 3736 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/830,189 | KELLEHER ET AL. | |
| | Examiner | Art Unit | |
| | Brian Szmal | 3736 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/6/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 30, 2009 has been entered.

### *Information Disclosure Statement*

2. The information disclosure statement filed August 6, 2009 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-14 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558) in view of Calancie et al (Stimulus-Evoked

EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation) in view of Katims (5,806,522).

Neubardt discloses a method for spinal screw insertion and further discloses applying an electrical stimulus to the first aspect of the bone; the electrical stimulus is emitted from an electrode disposed on the distal end of at least one of a probe and surgical tool; applying an electrical stimulus comprises applying a plurality of electrical stimulus pulses; the bone is disposed within one of the cervical, thoracic, and lumbar region of the patient's spine; the spinal nerve exits from successive vertebrae within one of the cervical, thoracic, and lumbar region of the patient's spine; the first aspect of the bone comprises a region within a pedicle in contact with a pedicle screw; and applying an electrical stimulus to the first aspect of the bone comprises applying the electrical stimulus to a proximal end of a bone screw inserted into the first aspect of the bone. See Figures 3 and 4; and Column 8, lines 59-67.

Neubardt however fails to disclose electrically monitoring a muscle myotome associated with the spinal nerve; automatically determining an onset neuro-muscular response to the application of the electrical stimulus to the first aspect of the bone by automatically increasing the electrical stimulus until the onset neuro-muscular response is detected; communicating to a surgeon operating on the patient’s spine an onset electrical stimulus level which causes the onset neuro-muscular response; the plurality of electrical stimulus pulses comprises current pulses that increase over time; the plurality of electrical stimulus pulses comprises current pulses that vary incrementally; the plurality of electrical stimulus pulses comprises current pulses varied incrementally

within a range from 0.5 to 32.0 milliamps; the onset neuro-muscular response is an electromyography response from a muscle coupled to the spinal nerve; electrically monitoring the muscle myotome is performed through the use of an electrode electrically coupled to the muscle myotome; the muscle myotome is disposed in one of the patient's legs; and the onset neuro-muscular response is determined by assessing whether the neuro-muscular response is greater than a predetermined onset level and increasing the electrical stimulus until the determined neuro-muscular response is greater than the predetermined onset level.

Calancie et al disclose a means for determining the evoked EMG during spinal fusion surgery and further disclose electrically monitoring a muscle myotome associated with the spinal nerve; automatically determining an onset neuro-muscular response to the application of the electrical stimulus to the first aspect of the bone by automatically increasing the electrical stimulus until the onset neuro-muscular response is detected; communicating to a surgeon operating on the patient's spine an onset electrical stimulus level which causes the onset neuro-muscular response; the plurality of electrical stimulus pulses comprises current pulses that increase over time; the plurality of electrical stimulus pulses comprises current pulses that vary incrementally; the plurality of electrical stimulus pulses comprises current pulses varied incrementally within a range from 0.5 to 32.0 milliamps; the onset neuro-muscular response is an electromyography response from a muscle coupled to the spinal nerve; electrically monitoring the muscle myotome is performed through the use of an electrode electrically coupled to the muscle myotome; the muscle myotome is disposed in one of

the patient's legs; and the onset neuro-muscular response is determined by assessing whether the neuro-muscular response is greater than a predetermined onset level and increasing the electrical stimulus until the determined neuro-muscular response is greater than the predetermined onset level. See pages 2780-2782.

Since both Neubardt and Calancie et al disclose means for monitoring stimulus evoked responses, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Neubardt to include the use of electrically monitoring the EMG response, as per the teachings of Calancie et al, since it would provide a more accurate means of monitoring the status of the pedicle screw in relation to the spinal nerve. It also would have been obvious to one of ordinary skill in the art to apply the monitoring means to the arms of the patient when working on the cervical spine.

Neubardt and Calancie et al however fail to disclose automatically increasing the electrical stimulus until a response is detected using a neurophysiology system; communicating to the surgeon includes visually displaying to the surgeon an intensity level representing the onset electrical stimulus level causing the onset neuromuscular response; and visually displaying involves the use of an integrated display.

Katims discloses an automated current perception threshold determination device and further discloses automatically increasing the electrical stimulus until a response is detected using a neurophysiology system; communicating to the surgeon includes visually displaying to the surgeon an intensity level representing the onset electrical stimulus level causing the onset neuromuscular response; and visually

displaying involves the use of an integrated display. See Figure 2; Column 7, lines 19-32; and Column 34, lines 9-23.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to change the manual operation as disclosed by the combination of Neubardt and Calancie et al, to an automatic operation, as taught by Katims, since the replacement of a manual operation with an automatic operation is a design consideration within the skill of the art. See In re Venner, 262 F.2d 91, 120 USPQ 192 (CCPA 1955).

5. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558), Calancie et al (Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation) and Katims (5,806,522) as applied to claim 14 above, and further in view of Neurovision SE Nerve Locator/Monitor.

Neubardt, Calancie et al and Katims, as discussed above, disclose a means of monitoring the muscle response of a stimulated nerve during spinal surgery, but fail to disclose illuminating lights; illuminating lights of varying colors; and each color corresponds to a predetermined warning to the user.

Neurovision SE discloses a means for stimulating and locating nerves and further discloses illuminating lights; illuminating lights of varying colors; and each color corresponds to a predetermined warning to the user. See Chapter 6: 6.1 and 6.2.

Since Neubardt, Calancie et al and Katims disclose means for visually alerting a user to the EMG status, but fail to disclose colored lights representing the measured status, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify the combination of Neubardt, Calancie et al and Katims to include the use of colored lights, as per the teachings of Neurovision SE, since it is well known to utilize colored lights to provide a warning.

6. Claims 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neubardt (5,474,558), Calancie et al (Stimulus-Evoked EMG Monitoring During Transpedicular Lumbosacral Spine Instrumentation) and Katims (5,806,522) as applied to claim 1 above, and further in view of Raymond et al (5,284,153).

Neubardt, Calancie et al and Katims, as discussed above, disclose a means for monitoring the EMG response to a stimulated pedicle screw, but fail to disclose the use of an audible indicator for indicating an intensity level of the response; sounding an alarm; varying the volume of the alarm; and varying the frequency of the alarm.

Raymond et al disclose a means of protecting nerves from injury during surgery, and further disclose the use of an audible indicator for indicating an intensity level of the response; sounding an alarm; varying the volume of the alarm; and varying the frequency of the alarm. See Column 7, lines 8-16.

It would have been obvious to one of ordinary skill in the art to modify the combination of Neubardt, Calancie et al and Katims to include the use of an audible indicator, as per the teachings of Raymond et al, since it would provide an additional means of alerting the user.

## ***Response to Arguments***

7. Applicant's arguments filed June 30, 2009 have been fully considered but they are not persuasive. The Applicants argue the combination of Neubardt, Calancie et al and Katims fail to teach the claim limitation of "automatically increasing said electrical stimulus **until said onset neuromuscular response is detected**, wherein the automatic increasing is controlled by said neurophysiology system". {emphasis added} The Applicants further argue Katims fails to teach the claimed limitation. The Examiner would like to respectfully point out the above rejection relies upon Calancie et al to teach the application of an electrical stimulus until an onset neuromuscular response is detected. The Examiner has relied upon Katims to teach the automatic increase of an electrical stimulus until a response is detected using a neurophysiology system. Modifying Calancie et al with Katims would yield the application of an electrical stimulation that automatically increases until an onset neuromuscular response is detected using a neurophysiology system.

***Conclusion***

8. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736